Comments of
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on
The Final Rule Implementing The Prescription Drug Marketing Act of 1987
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Docket No. 92N-0297

Public Citizen's Health Research Group appreciates this opportunity to comment on the very important consumer protection aspects of the final rule[1] implementing The Prescription Drug Marketing Act[2] (PDMA) of 1987. This law contains provisions intended to prevent the wholesale distribution and sale of subpotent, adulterated, counterfeit, or misbranded prescription drugs and bulk drug substances to the American public by requiring certain wholesalers, deemed "unauthorized distributors"[3] as opposed to "authorized distributors"[4], to produce a paper trail or "pedigree" documenting all prior sale, purchase, or trade of a drug, starting with the manufacturer. Unfortunately, Congress seriously erred in not mandating that all distributors, both unauthorized and authorized, be required to maintain such a pedigree for the drugs and bulk drug substances they sell. This has left the door open for unscrupulous distributors, even authorized ones, to "launder" counterfeit or substandard drugs that could be dispensed to an unsuspecting public.

The unequivocal resolution to this potentially hazardous loophole in the law in order to preserve Congress' intent in ensuring a prescription drug supply free of substandard, ineffective, or counterfeit drugs is a legislative "fix" that requires all distributors to maintain a pedigree for the drugs they sell. Any suggestion that PDMA should only be adjusted by altering the definition of an authorized distributor or that a unauthorized distributer need only to certify that drugs they sell originated with a manufacturer or authorized wholesaler only increases the number of distributers that could possibly launder substandard or counterfeit drugs. Such suggestions are, therefore, dangerous and irresponsible.

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[1] Department of Health and Human Services, Food and Drug Administration. Prescription Drug Marketing Act of 1987 – Final Rule. *Federal Register* Vol. 64 No. 232, pages 67720-67763, December 3, 1999.

[2] Public Law 100-293, Prescription Drug Marketing Act of 1987; April 22, 1988.

[3] An unauthorized distributor is defined in the FDA's final rule as " ... a distributor who does not have an ongoing relationship with a manufacturer to sell or distribute its products."

[4] An authorised distributor is defined in the FDA's final rule as " ... a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products."

In drafting PDMA in 1987, Congress found, in part, that:

1. American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

2. The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

3. The existence and operation of a wholesale submarket, commonly known as the "diversion market", prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

4. Large amounts of drugs are being reimported to the United States as American goods returned.

5. The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.[5]

Congress was provoked and acted responsibly, except for the authorized distributer omission mentioned above, in drafting and passing PDMA after several cases of drug counterfeiting were uncovered in the mid-1980s. One of these cases involved the importation and distribution of sixteen lots, comprising over one million tablets, of counterfeit Ovulen-21, an oral contraceptive in 1984. The counterfeit pills were found to be subpotent and two pregnancies were known to have occurred in women who used these pills.[6]

In our opinion, as the costs Americans pay for prescription drugs continue to skyrocket and as the disparity in these prices continues to grow in comparison to other countries the economic incentives for counterfeiting and selling substandard drugs increases proportionally. This incentive is now greater than ever before.

We fully support the Food and Drug Administration's (FDA) interpretation of PDMA that a person importing a prescription bulk drug substance into the United States intended for pharmacy compounding is engaged in wholesale distribution and must

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[5] Public Law 100-293, 1987, op. cit.

[6] Hearings before the Subcommittee on Oversight and Investigations of the Committee on energy and Commerce – House of Representatives. Prescription Drug Diversion and Counterfeiting – Part 2, July 1986, page 88.

provide a pedigree showing all prior sales and purchases of the prescription drug substance. Arguments by trade groups representing the nefarious pharmacy compounding industry that bulk drug substances were not intended by Congress to be covered by PDMA, are without serious merit. Their argument that a pedigree requirement for distributers of bulk drug substances will negatively impact the public's health by limiting the supply of these drugs from unknown sources is ludicrous.

Undoubtedly, there will be increased costs and logistical problems for distributors in meeting PDMA's pedigree requirements. In the long term, increased costs are always paid by consumers. Logistical problems in tracking the pedigree of drugs is not a legitimate reason for not requiring all distributors to maintain a pedigree. In 1999, 12.6 million units of blood were donated in the United States and each of these units can be processed into as many as four different blood products. Since the early 1990s, blood banks have been required for accreditation to track all products produced from a unit of blood and to be able to track each product back to the donor of the original unit of blood. In 1999, this amounted to keeping track of 23 million blood products.[7] Substandard blood and drugs both can have negative safety consequences for the public. If it is possible maintain a pedigree for every blood product in distribution, it is also possible to do so for drugs.

In closing, there is a possible additional benefit to the public if PDMA is legislatively amended to require all wholesale distributors of prescription drugs to maintain a pedigree. A pedigree requirement could be the basis for a more effective system of notification of pharmacies and patients of a drug recall. Now, for example, if a manufacturer or the FDA issues a drug recall on one or more lots of a prescription drug, a pharmacy will remove the implicated lots from its shelves. However, a pharmacy has no way of knowing if it may have dispensed recalled lots of a drug if the recall was issued after the pharmacy had dispensed all of its stock of the implicated drug. By having access to the pedigree information, through a wholesaler, a pharmacy could verify if it did, in fact, dispense a subsequently recalled drug and notify the patients who received the drug.

Public Citizen urges the FDA to work with Congress to close the serious loophole that now exists in PDMA.

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[7] Personal Communication with Eduardo Nunnes of the American Association of Blood Banks, October 26, 2000.